SOUTH AFRICAN VETERINARY COUNCIL

Veterinary Facility Evaluated:

Rule 31: Veterinary Laboratory Facilities

NAME OF THE FACILITY: _____

BY TICKING YES TO ANY RULE ON THIS CHECKLIST YOU AGREE THAT THE FACILITY ALREADY COMPLIES WITH THAT STANDARD.

31.		**A veterinary laboratory at or from which a registered person renders a laboratory service must:**					**OFFICE USE**
					YES	**NO**	**CATEGORY A, B or C**
	(1)	(a)		Be a permanent structure and any mobile unit operated from the facility shall be linked to permanent facility (see section on mobile units);			
		(b)		Have an external and internal neat appearance;			
		(c)		Have signage that complies with regulations of the local authority and where applicable also meets any regulation and / or Rules set by the Council;			
		(d)		Have separate areas for receiving members of the public and samples;			
		(e)		Have access to toilet facilities for members of the public;			
		(f)		As far as possible separate laboratory areas to prevent cross contamination of samples;			
		(g)		Have, where applicable, appropriate facilities for the storage of samples in order to prevent degradation of samples before testing;			
		(h)		Have facilities meeting the applicable regulations for the safe storage of chemicals and pharmaceuticals;			
		(i)		Have facilities for the safe storage of scheduled medicines, if applicable;			
		(j)		Have applicable equipment available to carry out the required tasks;			
		(k)		Have adequate facilities available for the washing, cleaning and sterilisation of all equipment;			
		(l)		Have proper facilities and containers for the storage of disposed hazardous waste including but not limited to sharps,			

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31.		A veterinary laboratory at or from which a registered person renders a laboratory service must:					OFFICE USE
					YES	NO	CATEGORY A, B or C
				chemicals, used test kits, biological samples, etc. prior to collection by a licensed waste removal company as per regulations of the local authority;			
		(m)		The internal walls, floors and work surfaces shall be of such a nature that they can be properly cleansed and disinfected in order to maintain hygienic conditions and prevent contamination of samples;			
		(n)		The drainage and washing water of a veterinary laboratory shall run into an adequate sewer and comply with the requirements of local authorities;			
		(o)		Where applicable make provision for the storage and disposal of carcasses in a manner that will ensure that they will not start to decompose before they are disposed of;			
		(p)		Where an on-site incinerator exists for the disposal of carcasses the incinerator shall be licensed according to the relevant environmental regulations;			
		(q)		Where applicable have animal housing that complies with relevant legislation;			
		(r)		Where applicable ensure that personnel are trained in the safe and humane handling of animals;			
		(s)		Employ personnel who are in possession of the applicable prescribed qualifications and are registered at the Council to perform the testing;			
		(t)		Provide personnel with protective clothing and protective equipment applicable to the level of risk involved; and			
		(u)		Have fire extinguishing apparatus which meets the requirements of the local authorities and is suited for the types of fire hazard based on the activities at the laboratory.			
	(2)			**Mobile laboratory units must:**			
		(a)		Be linked to a permanent facility and cannot be registered as an individual facility;			
		(b)		Be identified as a part of the permanent facility by listing the vehicle registration number at the time of applying for facility registration;			
		(c)		Comply with all applicable traffic regulations;			
		(d)		Be operated while in transit by a person with a driver's permit applicable to the type of vehicle;			
		(e)		Have a fire extinguishing apparatus which meets the requirements of the local authorities and is suited for the types			

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31.				A veterinary laboratory at or from which a registered person renders a laboratory service must:			OFFICE USE
					YES	NO	CATEGORY A, B or C
				of fire hazard based on the content of the mobile unit;			
		(f)		Have facilities for the safe transport and storage of chemicals and reagents that adhere to the regulations applicable to the transport of the chemicals and / or reagents;			
		(g)		Meet all the relevant regulations for transport of chemicals if applicable;			
		(h)		Have proper facilities for the storage of the sample types to be tested;			
		(i)		Have containers that meet the relevant regulations for disposal of hazardous waste including but not limited to sharps, chemicals, used test kits, biological samples, etc. until it can be discarded at or from the permanent facility; and			
		(j)		Have applicable equipment available to carry out the required tasks.			
	(3)			**The laboratory must comply with the following procedural aspects:**			
		(a)		The Laboratory must have a documented manual for Good Laboratory Practices (GLPs) stipulating the GLPs relevant to that Laboratory.			
		(b)		The Laboratory must have documented standard operating procedures for all tests performed at the facility;			
		(c)		Where international or national standardised methods exist, these must be used, unless reasonable ground for deviation exist;			
		(d)		The Laboratory must have a documented maintenance schedule for all equipment used in testing of samples and evidence that maintenance is done;			
		(e)		The Laboratory must have a documented calibration schedule for all applicable equipment used in testing of samples and evidence that calibration is done; and			
		(f)		The Laboratory must have a documented procedure for the retention of records including laboratory results that indicate how records will be secured, protected from loss and alterations, protected from unauthorised use and what the retention period will be.			
	(4)			**In addition to the minimum standards listed the following also apply as far as testing of patient samples and/or other samples are concerned:**			
		(a)		Any analysis performed to certify or confirm diagnosis of a controlled animal disease must be accredited by SANAS according to the latest version of the ISO 17025 standard and			

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31.		A veterinary laboratory at or from which a registered person renders a laboratory service must:			OFFICE USE		
					YES	NO	CATEGORY A, B or C
				upon accreditation of the analysis the laboratory facility must be approved by the Department of Agriculture, Forestry and Fisheries to perform the analysis; and			
		(b)		**Any in-house analyser used for testing patient samples must:**			
			(i)	Be maintained and service according to a documented schedule and evidence that this is done must be kept; and			
			(ii)	Be calibrated at a set and documented interval to ensure that the analyser can still detect all analytes accurately and evidence of the calibration shall be kept.			

Rule 6		Records at Veterinary Facilities					OFFICE USE
					YES	NO	CATEGORY A, B or C
	(1)			The attending veterinary professional (must) maintains records, including the records required in terms of the Medicines Act, for each animal **or** group of animals which are legible, accurate and permit prompt retrieval of information.			
	(2)			**Records must contain the following information for individual animals as applicable:**			
		(a)		the date or period of the examination or consultation;			
		(b)		name of the veterinarian who treated the patient;			
		(c)		client's identification;			
		(d)		patient name, other forms of identification, as well as the species, breed, gender and age;			
		(e)		clinical information for the purposes of continuous care and assessment;			
		(f)		vaccination record;			
		(g)		special procedures;			
		(h)		diagnosis;			
		(i)		treatment and scripts issued; and			
		(j)		discharge instructions.			
	(3)			**Records must contain the following information for production animals, including wildlife, as applicable:**			
		(a)		the date or period of the examination or consultation;			
		(b)		client's identification;			

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Rule 6		Records at Veterinary Facilities					OFFICE USE
					YES	NO	CATEGORY A, B or C
		(c)		species & breed; for wildlife species and sex, age group and/or colour if relevant;			
		(d)		procedures or treatment performed. For groups of animals a general description of the type of herd-work and bulk use of medicine is acceptable, but the use of schedule 5 and 6 wildlife capture medicines, must be recorded with care; and			
		(e)		instructions to client in general, if applicable and abnormal observations.			
	(4)			All records referred to in Rule 6(2), radiological images and the interpretation thereof, laboratory and pathology results must be retained by the principal of the veterinary facility for **a period of five years** from the patient's last visit, with the exception of ultrasound images where only the findings must be recorded.			
	(5)	**Records must contain the following information for diagnostic laboratory work (if) applicable:**					
		(a)		date sample was collected, date received, date completed, and date of release of results;			
		(b)		client information and geographical information;			
		(c)		animal identification as submitted, including species, breed, gender and age;			
		(d)		clinical history;			
		(e)		tests performed;			
		(f)		personnel doing the preparation and analysis;			
		(g)		method followed, deviations if any, reasons for deviation and reasons why results can still be accepted;			
		(h)		consumables and reagents including name, batch number, and expiry date;			
		(i)		results of quality control samples;			
		(j)		environmental conditions, if abnormal, or other critical information required by the standard operational procedure;			
		(k)		original findings; and			
		(l)		reports.			
	(6)			Records referred to in Rule 6(4) relating to a complaint, charge or allegation lodged with Council in terms of section 31(1) of the Act must be presented to Council within **seventy two (72) hours** of being requested to submit such records, or as otherwise arranged with Council.			
	(7)			Proper security arrangements must be made to protect medical and other clinical records from loss, fire, alterations, additions, supplements or unauthorised use; electronic records must be backed up on a daily basis and electronic backups should be stored off-site.			
	(8)			Any alterations, additions and/or supplements to any records, clinical			

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Rule 6		Records at Veterinary Facilities					OFFICE USE
					YES	NO	CATEGORY A, B or C
				or otherwise, must be entered as a supplement to said record and must be clearly defined as such.			
	(9)	(a)		The principal of a veterinary facility will be responsible for confirming the identity of the attending veterinary professional to Council, where a complaint is lodged against his/her veterinary facility.			
		(b)		The principal of a veterinary facility will be responsible for providing the records referred to in Rule 6(5), should a complaint be lodged against a veterinarian no longer in the employ of the principal of the facility, subsequent to the date on which the complaint originated.			
		(c)		Should the principal of a facility fail to comply with the provisions of Rule 6(9)(a) he/she will be held accountable for any unprofessional conduct arising from such a complaint.			

I, _____with SAVC registration number _____, confirm that the facility complies with the requirements as indicated in this self-evaluation form/s (minimum requirements checklist/s).

SIGNATURE (PRINCIPAL): _____ DATE: _____

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